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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MINNEAPOLIS, MN 55432-9924			EXAMINER MEHTA, BHISMA	
			ART UNIT 3767	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/695,848	Applicant(s) FEREK-PETRIC, BOZIDAR	
	Examiner BHISMA MEHTA	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The specification fails to disclose a method for treating a cancerous tumor via a wholly-implantable medical device and implanting an electroporation device wholly within a body. The specification also fails to disclose a wholly-implantable medical device which includes a drug reservoir and operative control circuitry both disposed within a housing for the device. The specification also fails to disclose delivering an electrical pulse with a pulse width of from about 50 ms to about 200 ms. The specification fails to disclose conveying a biological parameter to the operative control circuitry. The specification fails to disclose a method for treating cancer with a wholly-implantable medical device and implanting a wholly-implantable electroporation device within a body. The specification also fails to disclose at least one wholly-implantable lead and delivering a drug to the body via a fluid reservoir disposed within the wholly-implantable medical device.

In response to Applicant's remarks on page 7 and 8 traversing the objection to the specification, it is suggested that the language of the specification be amended to correspond with the specific language used in the claims.

Claim Objections

2. Claims 46-69 are objected to because of the following informalities: Claim 46 recites the limitation "said electrical pulse" in lines 10-12. Claim 58 recites the limitation "the at least one wholly-implantable therapy electrode" in lines 6-7. Claim 58 recites the limitation "said pulse" in line 11. There is insufficient antecedent basis for these limitations in these claims. It is suggested that "said electrical pulse" in claim 46 and "said pulse" in claim 58 be replaced with "said at least one electrical pulse". It appears that the word "strength" is missing after "field" in line 10 of claim 46 and in line 11 of claim 58. It appears there is a word missing after "implanting" in line 2 of claim 58. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 53, 68, and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 53, it is unclear if the drug catheter coupled to a housing is being claimed in addition to the fluid conduit and housing which is recited in claim 46. Additionally, it is unclear if the drug reservoir located within the housing in claim 53 is in addition to the drug reservoir within the housing in claim 46. In claims 68 and 69, it is unclear if the step of delivering at least one electrical pulse producing an electric field strength of about 700 V/cm to about 1500 V/cm and having a

pulse width of about 50 microseconds to about 200 microseconds is in addition to the electric field and pulse width already recited in claim 58.

Applicant's remarks on page 9 are unclear as no amendments to claims 53, 68, and 69 have been made which overcome the above rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 46-48, 50-53, 56, and 57 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitehurst et al (U.S. Patent No. 6,733,485). Whitehurst et al disclose a method of treating a cancerous tumor via a wholly-implantable medical device comprising a wholly-implantable electroporation device (150) which includes a drug reservoir (140) and operative control circuitry (145) both disposed within a housing (150). Whitehurst et al disclose implanting the wholly-implantable electroporation device (150) wholly within a body and delivering a drug to the body and proximate the tumor via a fluid conduit (141) coupled to the drug reservoir. Whitehurst et al also disclose delivering from the wholly-implantable electroporation device at least one electrical pulse across at least a portion of the cancerous tumor where the electric pulse

produces an electric field from about 700 V/cm to about 1500 V/cm and has a pulse width of from about 50 ms to about 200 ms (lines 12-24 of column 8). In lines 37-62 of column 18, Whitehurst et al disclose sensing at least one biological parameter and providing a sense signal based on the biological parameter and conveying the biological parameter to the operative control circuitry, thus controlling the delivery of the at least one electrical pulse based on the sense signal. Whitehurst et al disclose a method of treating a cancerous tumor by electroporation where the impedance of the tissue being treated is measured and the delivery of the electrical pulses is adjusted based on the comparison of the impedance measured to a threshold impedance value and a measurement of impedance across a portion of the cancerous tumor is used to determine if the electroporation procedure needs to be continued (lines 37-49 of column 18 and lines 12-66 of column 19). In lines 36-47 of column 12, Whitehurst et al teach delivering the drug via an external drug delivery apparatus. Whitehurst et al disclose delivering the drug through a drug catheter (132). Whitehurst et al teach programming the electroporation device to deliver a particular therapy profile or algorithm which may occur after implantation (lines 24-49 of column 18).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst et al in view of Hofmann (U.S. Patent No. 6,120,493). Whitehurst et al disclose the method substantially as claimed. However, Whitehurst et al are silent to the step of detecting a qRs complex from an electrocardiogram and synchronizing the delivering of the electrical pulses with the qRs complex. Hofmann discloses a method for treating a cancerous tumor by electroporation and further teaches detecting a qRs complex from an electrocardiogram during the delivery of electroporation pulses (lines 19-45 of column 17). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Whitehurst et al with the steps of detecting a qRs complex from an electrocardiogram as taught by Hofmann as Hofmann teaches that it is well known to monitor a patient's heart while the patient is undergoing the electroporation procedure.

9. Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst et al in view of Sterzer (U.S. Patent No. 5,386,837). Whitehurst et al disclose the method substantially as claimed. However, Whitehurst et al are silent to the step of increasing a temperature of the body near the tumor prior to delivering an electrical pulse. Sterzer discloses a method of treating a cancerous tumor such as a breast carcinoma by delivering a high frequency stimulus which increases the temperature at the site of the tumor (lines 45-68 of column 3), thus allowing the cells of the tumor to break down such that a chemotherapeutic drug can more easily enter the tumor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Whitehurst et al with the step of delivering

a high frequency stimulus to increase the temperature near the tumor as Sterzer teaches that it is well known to increase the temperature of the tumor as it will provide for better delivery of the chemotherapeutic drug into the cells of the tumor, and thus, this will provide for better treatment of the tumor when the electrical pulses of the electroporation procedure of Whitehurst et al are applied.

10. Claims 58, 59, 63-65, and 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver (U.S. Patent No. 5,389,069) in view of Sterzer. Weaver discloses a method for treating a cancerous tumor comprising implanting a wholly-implantable electroporation device in a body, delivering a drug (40) to the body, and delivering at least one electrical pulse across a portion of the tumor. Weaver also discloses the electroporation device as having at least one lead (20) with a therapy electrode (18) and delivering about one to about ten electrical pulses. Weaver discloses delivering electric pulses in the range of 100 volts to 1000 volts. Therefore, this is seen as delivering at least one electrical pulse producing an electric field strength of about 700 volts/cm to 1500 volts/cm as the actual electric field strength would be dependent on the relative location of the first and second electrode and of the size and location of the tumor being treated. Weaver also discloses delivering at least one electrical pulse of about 100 microseconds to about 1000 microseconds. The drug (40) is delivered via an external drug apparatus (42). In Figure 2, Weaver shows a drug catheter (54) coupled to a housing (62) of the electroporation device. Weaver teaches programming the electroporation device which may occur after implantation (lines 23-53 of column 4). Weaver discloses the method substantially as claimed. However,

Weaver is silent to the step of increasing a temperature of the body near the tumor prior to delivering an electrical pulse. Sterzer discloses a method of treating a cancerous tumor such as a breast carcinoma by delivering a high frequency stimulus which increases the temperature at the site of the tumor (lines 45-68 of column 3), thus allowing the cells of the tumor to break down such that a chemotherapeutic drug can more easily enter the tumor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Weaver with the step of delivering a high frequency stimulus to increase the temperature near the tumor as Sterzer teaches that it is well known to increase the temperature of the tumor as it will provide for better delivery of the chemotherapeutic drug into the cells of the tumor, and thus, this will provide for better treatment of the tumor when the electrical pulses of the electroporation procedure of Weaver are applied. As to claim 59, Sterzer discloses a controlled rise of the temperature of the tumor and also allowing for a high therapeutic temperature which is below a safe temperature. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made that by increasing the temperature of the tumor by applying the high frequency stimulus as taught by Sterzer would require sensing the temperature such that the temperature of the treated tumor can be kept at a safe level.

11. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver in view of Sterzer as applied to claim 58 above, and further in view of Hofmann.

Weaver in view of Sterzer disclose the method substantially as claimed. However, Weaver and Sterzer et al are silent to the step of detecting a qRs complex from an

electrocardiogram and synchronizing the delivering of the electrical pulses with the qRs complex. Hofmann discloses a method for treating a cancerous tumor by electroporation and further teaches detecting a qRs complex from an electrocardiogram during the delivery of electroporation pulses (lines 19-45 of column 17). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Weaver with the steps of detecting a qRs complex from an electrocardiogram as taught by Hofmann as Hofmann teaches that it is well known to monitor a patient's heart while the patient is undergoing the electroporation procedure.

12. Claims 61, 62, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver in view of Sterzer as applied to claim 58 above, and further in view of Whitehurst et al. Weaver in view of Sterzer disclose the method substantially as claimed. However, Weaver and Sterzer are silent to the step of measuring impedance across a portion of the tumor and comparing the impedance to a threshold impedance value and to the specifics of the cancerous tumor being an osteosarcoma. Whitehurst et al disclose a method of treating a cancerous tumor by electroporation where the impedance of the tissue being treated is measured and the delivery of the electrical pulses is adjusted based on the comparison of the impedance measured to a threshold impedance value (lines 37-49 of column 18 and lines 12-66 of column 19). Also, in lines 57-67 of column 8, Whitehurst et al teach treating an osteosarcoma or bone sarcoma. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Weaver with the step of measuring the impedance of the tumor as taught by Whitehurst et al as Whitehurst et al

teach that it is well known to use a measurement of impedance across a portion of the cancerous tumor to determine if the electroporation procedure needs to be continued. It also would have been obvious to one having ordinary skill in the art at the time the invention was made to use the method of Weaver to treat an osteosarcoma as taught by Whitehurst et al as both Weaver and Whitehurst et al teach using electroporation to treat cancerous tumors which can include osteosarcomas.

Response to Arguments

13. Applicant's arguments filed October 29 2007 have been fully considered but they are not persuasive. Applicant's arguments on pages 9-10 that Whitehurst et al and Weaver do not disclose a wholly-Implantable medical device for carrying out the claimed methods are not persuasive. In lines 43-50 of column 11, Whitehurst et al disclose that the wholly-implantable electroporation device (150) is sufficiently small such that it can be placed entirely within or wholly within the body of the patient such as entirely within the neoplasm or tumor. In lines 21-39 of column 3, Weaver discloses a wholly-implantable electroporation device which is implanted in a body (Figure 1 and 2).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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